

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Voluntary - Public

Date: 9/25/2009

GAIN Report Number: CH9076

China - Peoples Republic of

Post: Beijing

Licensing of Imported Food Without Domestic Standards

Report Categories:

FAIRS Subject Report

Approved By:

William Westman

Prepared By:

Mark Petry, Wu Bugang, Bao Liting, Katie Rohm

Report Highlights:

On August 13, 2009, the Ministry of Health (MOH) notified the World Trade Organization of draft "Rules on Administrative Licensing of Imported Food without National Food Safety Standards" for public comment. This measure has the WTO reference number G/SPS/N/CHN/119. Interested parties are encouraged to comment on the draft standard before October 12, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/119.

Executive Summary:

On August 13, 2009, the Ministry of Health (MOH) notified the World Trade Organization of draft national standard "Rules on Administrative Licensing of Imported Food without National Food Safety Standards" for public comment. This measure has the WTO reference number G/SPS/N/CHN/119. On the basis of the 2009 Food Safety Law, the rules apply to imported food that does not have a national food safety standard.

This is the second draft of this measure that has been released. The first draft was released on May 6 and was reported on in GAIN CH9051. Upon review, this second draft contains enough significant changes in comparison with the draft published in CH9051.

Interested parties are encouraged to comment on the draft standard before October 12, 2009. The date of

implementation for this measure is December 1, 2009. This report contains an UNOFFICIAL translation of G/SPS/N/CHN/119.

General Information:

Rules on Administrative Licensing of Imported Food without National Food Safety Standards

(Draft for comments)

Article 1 (Objective and basis of legislation) In an effort to enhance the administration of the imported food without national food safety standards and safeguard the consumer health, the Rules are established in accordance with the Food Safety Law of the People's Republic of China.

Article 2 (Definition) Imported food without national food safety standards refers to food produced and sold overseas as food for which China has not established corresponding food safety standards.

Article 3 The following items shall be administered in accordance with relevant regulations:

I. For food with a product standard, the standard shall apply. For food without a product standard, a general food standard (including standards for pesticide residues, veterinary drug residues, contaminants, mycotoxins, food additives, nutrition fortifiers, radioactive substances, etc.) shall apply.

II. For mixed (compound) raw materials dedicated to food production, all raw materials shall be permitted in China and shall comply with their respective standards. The mixed (compound) raw materials shall be implemented in accordance with enterprise standards to ensure that the final products meet the corresponding standards.

III. For items without a standard that are both food and drug, refer to Chinese Pharmacopoeia for relevant safety indicators.

IV. Raw materials for health food or new food (i.e., novel food, including products containing novel food materials) that have not been approved in China shall be administered in accordance with China's relevant regulations. Approved novel food and health food shall comply with corresponding requirements.

Foods that are beyond the above scope shall comply with the Rules.

Article 4 For specific procedures of application, acceptance, and review of the imported food without national food safety standards, refer to the relevant provisions of the Administrative Measures on Health Licensing and the Procedures for Licensing of Health-related Products.

Article 5 Importers selling or using the imported food without national food safety standards for the first time shall apply to the reviewing institution under the Ministry of Health before importation and shall provide the following documents:

1. Application form for administrative licensing of the imported food without national food safety standards;
2. Food formula or source of raw material, main ingredients and usage;
3. Production process;

4. Quality specification standards and inspection methods;
5. Relevant standards of international organizations or for other countries and their inspection methods;
6. Labels and instructions; and
7. In case of an authorized application, a certificate of authorization shall be provided.

If there are no relevant standards of international organizations or for other countries, the following shall be provided in addition to the above documents:

1. An inspection report on food safety indicators and safety information; and
2. Production and marketing certificates or an approval of use certificate.

Article 6 General requirements for application documents:

- I. In applying for a license for the imported food without national food safety standards, one copy of the original application documents and four duplicates shall be provided;
- II. In addition to inspection reports and official supporting documents, the official seal of the applicant shall be affixed to each page of the original application documents;
- III. Documents must be printed on A4 size paper with evident labels differentiating each items, arranged documents in the provided order, and bind into books;
- IV. Use China's legal units of measurement;
- V. The application documents shall be complete, clear and the same items shall be filled in consistently;
- VI. Any foreign language in the application documents shall be translated into standard Chinese and the translation shall be attached on top of the corresponding foreign language documents unless they are an ingredient name, person's name, or foreign address in English or Latin as required by the Rules; and
- VII. The application documents shall be truthful, legitimate, and valid. The duplicates shall be reproduced from their originals and shall be completely identical to the originals.

Article 7 A certificate by the relevant department or institution of the producing country (region) or exporting country (region) shall be issued to allow production and marketing in the country (region) and shall meet the following requirements:

- I. The certificate shall be issued by the competent government department or trade association of the producing country or country (region) of origin. If the original copy cannot be supplied, a duplicate shall be sufficient, provided that the duplicate is notarized by a local institution and certified by the Chinese Embassy in the producing country or country of origin, or the duplicate has been confirmed by the issuing organization.
- II The certificate shall indicate product name, manufacturer, name of the issuing organization, and the date of issuance with an official stamp or signature of the legal representative (or his/her authorized person);
- III. The indicated product name and manufacturer shall be completely identical to the content in the application documents;
- IV. If one certificate covers multiple products and more than two of them need to be reported, the application shall be made at the same time. The original certificate shall be provided for one product with duplicates for all other products. However, a written statement shall be provided to indicate with which the original certificate is attached;
- V. In case no certificates can be submitted, the Ministry of Health may audit the production site.

Article 8 The supplementary documents submitted shall meet the following requirements:

I. A complete copy of the original supplementary document shall be submitted with the date and the seal of the applicant shall be affixed to each page of the supplementary documents;

II. After receiving the Notice of Extension of the Technical Review of Administrative Licensing, the applicant shall submit supplementary documents within a year, or the applicant shall be deemed to terminate the application.

Article 9 After receiving the application for the imported food without national food safety standards, the reviewing institution of the Ministry of Health shall make a decision on whether to accept the application on the spot or within five working days.

Article 10 The reviewing institution of the Ministry of Health shall review the application documents within 60 days after receiving the application.

Article 11 The Ministry of Health shall organize the experts on food hygiene, toxicology, nutrition, microbiology, processing, and chemistry to review and assess the application documents.

If standards of relevant international organizations or for other countries, Chinese standards for like products, or enterprise standards are applicable after experts' review and assessment. The Ministry of Health may identify relevant standards for implementation.

Article 12 During the review process, the representative of the applicant shall be ready to answer any technical questions upon request by the reviewing institution of the Ministry of Health, but he/she shall not participate in the review.

Article 13 All application documents and samples related to the imported food without national food safety standards shall not be returned to the applicant before the Ministry of Health has made a conclusion on the review.

To terminate the application for the imported food without national food safety standards, an importer may request in writing to retrieve the letter of authorization and the certificate permitting production and marketing in the producing country (region) (not including the certificate covering multiple products that are submitted for application at the same time), or the certificate for approved use and the notarization document.

Article 14 During the review process, if the applied product is determined to fall into the list as described in Article 3 that may be implemented in accordance with other laws and regulations, the reviewing institution shall notify the applicant and terminate the review and approval process. It shall encourage the applicant to apply in accordance with relevant administrative licensing.

Article 15 Based on the assessment result of the experts, the Ministry of Health shall make a decision in accordance with relevant laws and regulations.

The Ministry shall publish the list and safety indicators of the imported food without national food safety standards in the form of an announcement.

If the imported food without national food safety standards does not meet the requirements, the Ministry shall notify the applicant in writing of a disapproval decision with reasoning.

Article 16 The Ministry of Health may organize experts to re-evaluate the approved imported food without national food safety standards in one of the following circumstances:

I. As science and technology develop, the knowledge about the safety of the approved imported food without national food safety standards has changed;

II. The safety of the imported food without national food safety standards is under question; or

III. An re-evaluation is required for the imported food without national food safety standards by the supervision and for testing purposes.

If the imported food without national food safety standards fails in the re-evaluation process, the Ministry of Health shall have the right to announce a prohibition to its operation and use.

Article 17 The Ministry of Health is responsible for the interpretation of these Rules.

Article 18 The Rules shall come into force upon publication.

Annex: Application for Administrative Licensing of the Imported Food without National Food Safety Standards

Prepared by the Ministry of Health of the People's Republic of China

Completion Notes

1. This Application may be downloaded from the Ministry of Health web site or the Health Supervision Center web site under the Ministry of Health.

Website: <http://www.moh.gov.cn> or <http://www.jdzx.net.cn>

2. The content in this Application and all the application documents must be printed.

3. The content in this Application shall be complete, clear and shall not be altered.

4. Before filling out this Application, please read relevant regulations and the provisions on declaration acceptance carefully.

Product name	Chinese				
	English				
Manufacturer	Name	Chinese			
		English			
	Address			Country (Region)	
	Tel		Contact person		
Declaration unit	Name				
	Address				
	Contact person		Tel		
Authorized agency	Name				
	Address				
	Contact person		Tel		

Guarantee

As a product applicant, we guarantee that the content declared in this Application and the information attached hereto are true and legitimate, that the duplicates and the originals are consistent and that the data in the attached documents are that obtained from research and detection. If the above guarantee is untrue, I would like to assume the corresponding legal liability and all the consequences caused thereby.

Applicant (seal)

Legal representative (signature)

Date:

Attached information (please mark "✓" in the ☐ before the provided information)

- ☐1. Application for administrative licensing of the imported food without national food safety standards;
- ☐2. Food formula or source of raw material, main ingredients and uses;
- ☐3. Production process;
- ☐4. Quality specification standards and inspection methods;
- ☐5. Standards of international organizations or other relevant national standards and inspection methods;
- ☐6. Labels and instructions;
- ☐7. In case of authorized application, a letter of authorization shall be provided.

In case of no standards of international organizations or other relevant national standards, the following shall be provided in addition to the above-mentioned documents:

- ☐8. An inspection report on food safety indicators and safety information;
- ☐9. Production and marketing certificates or a certificate for approved use.

Other issues required to be explained:

END TRANSLATION